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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hassan Mostafavi

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EXAMINER

LAURITZEN, AMANDA L

ART UNIT

PAPER NUMBER

3737

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,920	Applicant(s) MOSTAFAVI, HASSAN	
	Examiner Amanda L. Lauritzen	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009 and 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,31-51,53-55,57-60 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29,31-51,53-55,57-60 and 62-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to communications filed 08 July 2009. Amendments to the claims are not interpreted to introduce new matter. The rejection under 35 U.S.C. 112 for new matter is withdrawn in view of the amendments. Terminal disclaimers filed 08 July 2009 are deficient because the attorney listed does not have power of attorney (see Power of Attorney filed 12 January 2004). Therefore the terminal disclaimer was not approved and the associated double patenting rejections are repeated herein as appropriate.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 July 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to rejection under 35 U.S.C. 101 for non-statutory subject matter have been fully considered but they are not persuasive. The pertinent rejection(s) are reformulated herein in view of the updated guidelines.

Applicant's arguments with respect to the combination of Kaufman and Takeo have been fully considered and are persuasive. It is conceded that neither Kaufman nor Takeo teaches triggering a medical procedure based on an image; however, upon further consideration, new grounds of rejection are presented taking into account the teachings of Kalend et al. (US

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5,784,431) and Takai et al. (US 7,221,733) for expressly teaching gating of a radiation therapy in response to an image.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US 7,006,862) in view of Takeo (US 6,125,166) and Kalend et al. (US 5,784,431).

Kaufman discloses a system and associated method in which radiation therapy is gated by an ECG signal, that involves at least first and second real-time images and forming a composite image with thresholding pixel (contrast) values in the activation/deactivation of a therapeutic radiation (abstract; Fig. 16; col. 5; col. 14; col. 20, lines 16-23; col. 3, lines 32-45; col. 8, lines 8-14; col. 13, lines 24-33; col. 2, lines 57-64; col. 9, lines 10-17; inter alia).

Kaufman et al. do not expressly teach conducting a subtraction operation among images, but where Kaufman is deficient, Takeo establishes what is conventional within the skill of the art. Takeo discloses a method of forming energy subtraction images and discloses using contrast values to determine threshold values (col. 1, lines 50-64 for the subtraction process; also col. 19, lines 11-28 in which a contrast value is used).

Neither Kaufman et al. nor Takeo expressly teach gating of a medical procedure based at least in part on an image or images, but Kalend et al. establish that it is well known to track

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motion with successive images for gating of a radiation beam (cols. 3-4, line 67 and 1-3, respectively).

It would have been obvious to use a contrast value of the image for reference as taught by Takeo in the system of Kaufman et al. for determining a threshold value and to gate based at least in part on the image, as taught by Kalend et al., as gating a radiation procedure based on successive images enables tracking of patient motion due to breathing, for example, such that the radiation is directed to the target site.

The control of radiation therapy based on a series of images, as in Kalend et al. is understood to be accomplished using a processor. It is necessarily understood to be real time in order to successfully target the region of interest as coincident with patient motion due to breathing, for example.

2. Claims 24-29, 32, 33, 34-39, 40-48 and 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Takeo and Kalend et al., as applied in section 1 above, further in view of Fitzgerald (US 2005/0027196).

Kaufman et al. as appended by Takeo and Kalend et al. includes all features of the invention as substantially claimed, including enhancing a moving object except for providing templates that include both image and radiation treatment data. In the same field of endeavor, Fitzgerald teach where Kaufman, Takeo and Kalend et al. are deficient – specifically providing templates, records or what is generally known as a radiation treatment plan that prescribes imaging information and information related to radiation therapy [0012], [0023]. The templates of the claims is corresponded to the treatment planning records of Fitzgerald. The treatment planning record includes both image and treatment data [0012]. Additionally, [0014] presents

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that treatment plans include a visual representation of the radiation dose distribution (an image), with the dose being treatment data. Multiple radiation plans are disclosed at [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to provide templates specific to both the imaging and radiation therapy protocol for the purpose of planning guided treatment, as taught by Fitzgerald.

Regarding claims 24 and 34, the gating of a therapeutic radiation disclosed in Kalend et al. is understood to include adjustment of more than one parameter related to the radiation treatment, including both the alignment of the beam and the on/off status, at the very least.

Regarding claims 49-66, Fitzgerald teaches tracking the position of a target area in that the treatment planning accommodates tracking the location and disposition of a radiation beam with respect to a target anatomical area [0022]. The position of sources is verified with an imaging step [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to include position tracking, as taught by Fitzgerald, in the radiation therapy gating scheme of Kaufman et al. as appended by the image subtraction scheme of Takeo and the gating of therapeutic radiation based on a series of images of Kalend et al. Additionally, the method of Kaufman et al. is specific to synchronizing with respect to phases of the cardiac cycle, which implies a template to align the characteristic phases (col. 8, lines 8-12; also col. 10, lines 57-61 for slice alignment with the R-R cycle). Template matching is additionally inferred from the monitoring of duration of the R-R cycle in Kaufman et al. (col. 11, lines 33-43).

3. Claims 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Takeo and Kalend et al., as applied in section 1 above, further in view of Verard et al. (US 2004/0097805).

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Kaufman et al. as appended by Takeo and Kalend et al. include all features of the invention as substantially claimed, including enhancing a moving object except for providing templates that include both image and treatment data. In the same field of endeavor, Verard et al. disclose registration images with templates (para. 112 and para. 132 in which templates provide treatment data that includes lead placement and para. 146 for templates that provide therapy effective zones). It would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated template registration as taught by Verard et al. with the system of Kaufman et al. in order to optimize the procedure (for motivation, see Verard para. 146). Takeo et al. teach image averaging for the purpose of smoothing an image (col. 13, lines 36-46). It would have been obvious to incorporate image averaging as taught by Takeo with the modified system of Kaufman et al. in order to smooth images in the sequence. Features in the depending claims are clearly taught in the references applied or are considered to be obvious within the skill of the art.

4. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takai et al. (US 7,221,733) in view of Takeo (US 6,125,166).

Takai et al. disclose a method for physiological gating of a therapeutic radiation in which information from subsequent images of the target region is used to control the radiation beam, in response to movement of the object. Takai et al. do not specifically address image processing between subsequent images, but Takeo teaches details of energy subtraction images and discloses using contrast values to determine threshold values (col. 1, lines 50-64 for the subtraction process; also col. 19, lines 11-28 in which a contrast value is used). It would have

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been obvious to one ordinarily skilled in the art to make use of the image subtraction algorithm taught in Takeo to better visualize movement of the target upon which the gating of the therapeutic radiation is based, in Takai et al.

5. Claims 24-29, 32, 33, 34-39, 40-48 and 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takai et al. in view of Takeo, as applied in section 4 above, further in view of Fitzgerald (US 2005/0027196).

Takai et al. as appended by Takeo includes all features of the invention as substantially claimed, including enhancing a moving object in a series of images except for providing templates that include both image and radiation treatment data. In the same field of endeavor, Fitzgerald teach where Kaufman, Takeo and Kalend et al. are deficient – specifically providing templates, records or what is generally known as a radiation treatment plan that prescribes imaging information and information related to radiation therapy [0012], [0023]. The templates of the claims is corresponded to the treatment planning records of Fitzgerald. The treatment planning record includes both image and treatment data [0012]. Additionally, [0014] presents that treatment plans include a visual representation of the radiation dose distribution (an image), with the dose being treatment data. Multiple radiation plans are disclosed at [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to provide templates specific to both the imaging and radiation therapy protocol for the purpose of planning guided treatment, as taught by Fitzgerald.

Regarding claims 24 and 34, the gating of a therapeutic radiation disclosed in Takai et al. is understood to include adjustment of more than one parameter related to the radiation treatment, including both the alignment of the beam and the on/off status, at the very least.

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Regarding claims 49-66, Fitzgerald teaches tracking the position of a target area in that the treatment planning accommodates tracking the location and disposition of a radiation beam with respect to a target anatomical area [0022]. The position of sources is verified with an imaging step [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to include position tracking, as taught by Fitzgerald, in the radiation therapy gating scheme of Takai et al. as appended by the image subtraction scheme of Takeo. Features in the depending claims are clearly taught in the references applied or are considered to be obvious within the skill of the art.

6. Claims 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takai et al. in view of Takeo, as applied in section 4 above, further in view of Verard et al. (US 2004/0097805).

Takai et al. as appended by Takeo include all features of the invention as substantially claimed, including enhancing a moving object except for providing templates that include both image and treatment data. In the same field of endeavor, Verard et al. disclose registration images with templates (para. 112 and para. 132 in which templates provide treatment data that includes lead placement and para. 146 for templates that provide therapy effective zones). It would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated template registration as taught by Verard et al. with the system of Takai et al. in order to optimize the procedure (for motivation, see Verard para. 146). Takeo teaches image averaging for the purpose of smoothing an image (col. 13, lines 36-46). It would have been obvious to incorporate image averaging as taught by Takeo with the modified system of Takai et

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al. in order to smooth images in the sequence. Features in the depending claims are clearly taught in the references applied or are considered to be obvious within the skill of the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-29 and 31-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7-63 of copending Application No. 10/656,478. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to gating a medical procedure based on an image (and/or composite image), with method steps and system components that are identical or obvious variants. It is noted that the instant claims do not specify determining a position of a target region, but based on the conflicting application it is clear that this is accomplished based on the resulting composite subtraction image.

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2. Claims 1-29 and 31-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-43 and 44-49 of copending Application No. 10/678,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to gating a medical procedure based on an image or, in the case of the conflicting claims, based on first and second data signals, which encompasses images.

The above (sections 2 and 3) are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

3. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of US 6,959,266. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims.

4. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of US 6,937,696. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims. Additionally, the conflicting method is executed in the context of a computed tomography procedure, as in the preamble of claim 1, so it is reasonably assumed that the first and second sets of data as claimed, could correspond to first and second tomographic image datasets.

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5. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of US 6,621,889. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-9, 64, 15-23, 66, 24-29, 31-33, 40-48, 49-51, 53, 54 and 58-63 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In order for a process claim to be patentable under 35 U.S.C. 101, it must be tied to another statutory class (such as a particular apparatus), or transform underlying subject matter (such as an article or materials) to a different state or thing. The claim(s) must positively recite the thing or product to which the process is tied, for example, by identifying the specific apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example, by identifying the material that is being changed to a different state (see *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385, Fed. Cir. 2008. See also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for hearing *en banc* pending).

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In this case, the claims do not positively recite use of a particular apparatus to carry out the step(s) of providing a real-time image, as there is not recitation of any image acquisition apparatus. Additionally, the processor set forth in the preamble, as applicable to claims 1, 15, 24, 31, 40, 49 and 58, does not positively set forth sufficient link to an apparatus and it is understood that what is recited in the body of the claim(s) can be accomplished as a purely mental or human process. For these reasons, there is not sufficient tie of the claimed subject matter to another statutory class.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yi et al. (US 7,609,810), Yan et al. (US 7,349,522) are cited as relevant to methods making use of an image or images to gate a medical procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda L. Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
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